BLUE ICE- menthol gel JT Cosmetics and Chemicals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BLUE ICE

Diva Blue Ice is a cool, greaseless pain reliever. It penetrates deep into skin for fast, temporary relief of minor aches and pains in muscles and joints. It provides cooling, soothing relief that lasts for hours.

Drug Facts

Active Ingredients

Menthol 2%

Purpose

Topical Analgesic

Keep out of reach of children.

Usage:

Provides temporary relief of minor aches and pains in muscles and joints associated with simple backache, strains, sprains, arthritis and sports injuries.

Warning

For External use only. Not for internal use.

Use only as directed. Avoid contact with eyes or mucous membranes. Do not apply to open wounds or damaged skin. Make sure skin is clean and free from any creams, ointments, sprays or liniment. Do not bandage.

Do not use with heating pads or heating devices.

If condition worsens of symptoms persist for more than 7 days or if symptoms disappear and occur again within a few days, discontinue use and consult a physician. If you have sensitive skin, consult a physician before use. If skin irritation develops, discontinue use and consult a physician. If you are pregnant or nursing a baby, consult your doctor before use.

Direction

Clean skin of all other lotions, cream ointments, liniment or sprays. Apply liberally to affected area and massage until gel is absorbed into skin. Do not apply more than 3 or 4 times daily. No protective cover needed. Do not apply to children under 2 years of age.

Inactive Ingredients:

Water, Isopropyl Alcohol, Camphor, Carbomer, Sodium Hydroxide, Methylchloroisothiazolinone & Methylisothiazolinone, Blue 1 (CI 42090).

Do not use, store, pour or spill near heat or open flame. Store in a cool, dry place and keep lid tightly

closed.

Distributed by

JMD ALL STAR IMPEX INC.,

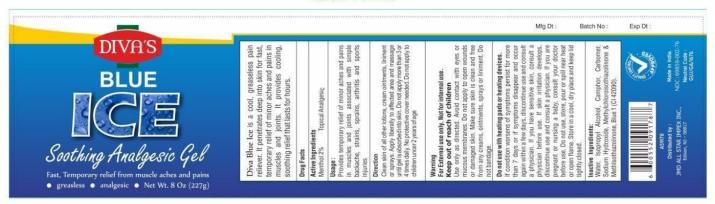
Edison, NJ - 08817

Made in India.

Neutral Code: GUJ/GA/1676

Packaging

FRONT PANEL



DRUG FACTS LABELING

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BLUE ICE

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69859-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL, UNSPECIFIED FORM	2 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
CAMPHOR (NATURAL) (UNII: N20 HL7Q941)		
CARBOMER HO MO PO LYMER TYPE C (UNII: 4Q93RCW27E)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
METHYLCHLORO ISOTHIAZO LINO NE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:69859-002-76	227 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	05/23/2015		

Labeler - JT Cosmetics and Chemicals (650884849)

Establishment				
Name	Address	ID/FEI	Business Operations	
JT Cosmetics and Chemicals		650884849	manufacture(69859-002)	

Revised: 6/2015 JT Cosmetics and Chemicals